510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:
k042421

B. Purpose for Submission:
New submission for the Uritek 151 Urine Analyzer for use with Teco Diagnostic's previously cleared urine test strips URS-10 k970250. Urinary Glucose and Blood are class II and the subject of the review on the Uritek 151 analyzer.

C. Measurand:
Glucose, Blood, Leukocytes, Specific Gravity, pH, Nitrite, Protein, Ketone, Urobilinogen, and Bilirubin, in urine

D. Type of Test:
Qualitative/Semi-Quantitative

E. Applicant:
TECO DIAGNOSTICS

F. Proprietary and Established Names:
URITEK 151 URINE ANALYZER, MODEL TC-151

G. Regulatory Information:

1. Regulation section:

Measurand

21 CFR §	862.1340	Urinary glucose (nonquantitative) test system.
21 CFR §	864.6550	Occult blood test.
21 CFR §	864.7675	Leukocyte peroxidase test.
21 CFR §	862.2800	Refractometer for clinical use.
21 CFR §	862.1550	Urinary pH (nonquantitative) test system.
21 CFR §	862.1510	Nitrite (nonquantitative) test system.
21 CFR §	862.1645	Urinary protein or albumin (nonquantitative) test system
21 CFR §	862.1435	Ketones (nonquantitative) test system.
21 CFR §	862.1785	Urinary urobilinogen (nonquantitative) test system.
21 CFR §	862.1115	Urinary bilirubin and its conjugates (nonquantitative) test system.

Analyzer

21CFR §	862.2900	Automated urinalysis system.

2. Classification:
Class II, I

3. Product code:

JIL	ENZYMATIC METHOD, GLUCOSE (URINARY, NON-QUANT.)
JIO	BLOOD, OCCULT, COLORIMETRIC, IN URINE
LJX	TEST, URINE LEUKOCYTE
JRE	REFRACTOMETER FOR CLINICAL USE
CEN	DYE-INDICATOR, PH (URINARY, NON-QUANT.)
JMT	DIAZO (COLORIMETRIC), NITRITE (URINARY, NON-QUANT)
JIR	INDICATOR METHOD, PROTEIN OR ALBUMIN (URINARY, NON-QUANT.)
JIN	NITROPRUSSIDE, KETONES (URINARY, NON-QUANT.)
CDM	DIAZONIUM COLORIMETRY, UROBILINOGEN (URINARY, NON-QUANT.)
JJB	AZO-DYES, COLORIMETRIC, BILIRUBIN & ITS CONJUGATES (URINARY, NON-QUANT.)
KQO	AUTOMATED URINALYSIS SYSTEM respectively

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   see Indication(s) for use
2. Indication(s) for use:
   The Uritek-151 Urine Analyzer is intended for use with Teco Urine Reagent Strips for Urinalysis such URS-10, used in the determination of glucose, protein, pH, bilirubin, blood, ketone, urobilinogen, nitrite, specific gravity, and leukocytes in urine.
3. Special conditions for use statement(s):
   for prescription use
4. Special instrument requirements:
   URITEK 151 URINE ANALYZER, MODEL TC-151

I. Device Description:

URITEK-151 Urine Analyzer is designed combining optics, electronics, and computer technology with other technologies. The super-high cold light source testing used in the optical system, enhances the discerning ability and reduces the influence of ambient light on test. The modular system design and large-scale integrated circuit reduces the interference of each fixture of system and improve its reliability and stability.

The instrument applies to two monochromatic light beams scanning one at a time the different reaction pads, and transforms optical signals into electrical signal. The controlling system processes the electrical signal and computes the reflectance ratio of testing color according to the following equation:

$$R(\%) = \frac{Tm \times Cr}{Tr \times Cm} \times 100\%$$

R -- Reflectance ratio

Tr -- Reflectance intensity of reference light of test sector

Cr --Reflectance intensity of reference light of blank sector

Tm -- Reflectance intensity of test sector of test light

Cm -- Reflectance intensity of blank sector of test light

Comparison of the Reflectance ratio for each pad with internal standards produces a clinical value for each of the tests in the strip. The results can be visually read and printed.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Bayer, Clinitek 50 Urine Chemistry Analyzer

2. Predicate 510(k) number(s):
   k960546
3. Comparison with predicate:

Comparison		
Item	Device	Predicate
Intended use	Used in the determination of glucose, protein, pH, bilirubin, blood, ketone, urobilinogen, nitrite, specific gravity, and leukocytes in urine.	Same
Basic Operating Principle	Reflectance	Same
Testing Options	Single-step or continuous testing	Same
Test steps	Dip, and place urine strip onto test table	Same
Printer	Internal or external	Same
Environment Requirement	0-40 ^{o}C Relative humidity ≤ 85%	18-30 ^{o}C Relative humidity 20 - 85%
Power Source	A110V (± 10%), 50 Hz (± 1 Hz) Input: 30VA	Input: 100 – 250 V, 50/60 Hz, 0.5 – 0.3 A Output: +9 V, 2.78 A
Dimension	350 x 315 x 130 mm	23.5 x 15.2 x 15.5 cm
Weight	4.0 kg	1.25 kg
Calibration	Self-calibrating – white calibration bar	Same

K. Standard/Guidance Document Referenced (if applicable):

None Referenced

L. Test Principle:

The instrument applies to two monochromatic light beams scanning one at a time the different reaction pads, and transforms optical signals into electrical signal. The controlling system processes the electrical signal and computes the reflectance ratio of testing color according to the following equation:

$$R(\%) = \frac{Tm \times Cr}{Tr \times Cm} \times 100\%$$

R -- Reflectance ratio

Tr -- Reflectance intensity of reference light of test sector

Cr --Reflectance intensity of reference light of blank sector

Tm -- Reflectance intensity of test sector of test light

Cm -- Reflectance intensity of blank sector of test light

Comparison of the Reflectance ratio for each pad with internal standards produces a clinical value for each of the tests in the strip. The results can be visually read and printed.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The repeatability study is performed with 20 replications on three levels of controls. The contingency table 2x2 is applied to evaluate the total agreement, in term of percentage, on each parameter. The ±20% Cutoff is used as the breaking point between high positive and low negative samples.

Control I				
Samples	**Glu**		**Bld**	
Cutoff	797.9mg/dL		152cells/µl	
	Pos	Neg	Pos	Neg
Positive	20	0	20	0
Negative	0	20	0	20
Agreement %	**100%**	**100%**	**100%**	**100%**

Control II				
Samples	**Glu**		**Bld**	
Cutoff	305.5mg/dL		18cells/µl	
	Pos	Neg	Pos	Neg
Positive	20	1	20	1
Negative	0	19	0	19
Agreement %	**100%**	**95%**	**100%**	**95%**
Control III				
Samples	**Glu**		**Bld**	
Cutoff	80.2mg/dL		3cells/µl	
	Pos	Neg	Pos	Neg
Positive	20	0	20	0
Negative	0	20	0	20
TOTAL	20	20	20	20
Agreement %	**100%**	**100%**	**100%**	**100%**

b. Linearity/assay reportable range:

See k970250

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

See k970250

d. Detection limit:

See k970250

e. Analytical specificity:

See k970250

f. Assay cut-off:

See k970250

2. Comparison studies:

a. Method comparison with predicate device:

The comparison is performed by using the Teco strips (Lot#:E48051 Exp.:08/06) on Uritek-151(SN:30376) verses the Bayer Multistix 10SC Reagent strips(Lot#:2K02C Exp.:04/06) on Clinitek-151(S/N:6510A141818) patient samples are tested on both the analyzers. The data is analyzed with 2 contingency tabular formats and divided into two levels of percentage agreement: table 1) all the positive and negative samples, 2) every range measurement.

Glucose

2x2 Contingency Comparison

Clinitek-50 TC-151	Positive	Negative
+ve	72	1
-ve	3	24
TOTAL	75	25
Agreement %	96%	96%

Range Comparison

Clinitek-50 TC-151	1000	500	250	100	0
1000	18				
500	0	18			
250		1	18	1	
100			1	18	1
0					24
TOTAL	18	19	19	19	25
Agreement %	100%	95%	95%	95%	96%

Blood

2x2 Contingency Comparison

Clinitek-50 TC-151	Positive	Negative
+ve	73	1
-ve	2	24
TOTAL	75	25
Agreement %	97%	96%

Range Comparison

Clinitek-50 TC-151	200	80	25	10	0
200	17				
80	1	17	1		
25		1	18	1	
10				19	1
0					24
TOTAL	18	18	19	20	25
Agreement %	94%	94%	95%	95%	96%

b. Matrix comparison:
Not Applicable

3. Clinical studies:
   a. Clinical Sensitivity:
   Not Applicable
   b. Clinical specificity:
   Not Applicable
   c. Other clinical supportive data (when a. and b. are not applicable):
   Not Applicable
4. Clinical cut-off:
   Not Applicable
5. Expected values/Reference range:
   See k970250

N. Instrument Name:

URITEK 151 URINE ANALYZER, MODEL TC-151

O. System Descriptions:

1. Modes of Operation:
   Single-step or continuous testing
2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
   Yes ____X___ or No _____
3. Specimen Identification:
   Manual Patient ID entry
4. Specimen Sampling and Handling:
   Manually Dip, and place urine strip onto test table
5. Calibration:
   Uritek-151 is a self-calibrated analyzer every time power is turn on. The calibration is performed twice when the strip bed moves in-out two times. As a preliminary step, ensure steady position of strip bed and clean the calibration white dot.
6. Quality Control:
   1. Positive and negative controls are always recommended for testing purpose.
   2. Use HYCO® KOVA three levels controls: High Abnormal, Abnormal, and Normal.
   3. Prepare the controls accordingly to the instruction insert provided.
   4. Test the urine strips with the controls. Perform the control testing according to the sample test instructions.
   5. Record the results and compare to the ranges provided. *Remark: The control testing is only requested on every 100 tests or after turn on the power.*
   6. Retest the controls with different lot of strips, if test results are in doubt. If the test results are consistently in doubt, please contact TECO technical support for help.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Software documentation provided demonstrates the Uritek 151 Urine Analyzer was designed and manufactured under well developed software lifecycle processes.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.